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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,646	12/14/1999	GARY R. GROTENDORST	FIBRO1130	4092

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EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	

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21

Please find below and/or attached an Office communication concerning this application or proceeding.

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/6/02

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.
Of the above, claim(s) 6-14 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) ~~5~~ 1-5, 15-18 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-18 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ *Notice of Reference Cited*, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Part III: Detailed Office Action

Claims 1-5 have been amended. Claims 1-5 and 15-18 are under consideration.

The claims as amended are in full compliance with 37 C.F.R.§1.821(d).

The rejection of claims 1-5 under 35 U.S.C. § 101 is withdrawn in view of applicants' arguments and/or amendments.

Objections and Rejections under 35 U.S.C. §112:

Claims 2-4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 requires that the claimed protein *comprise* the amino acid sequence of SEQ ID NO: 4, whereas claims 2-4 require only portions of that sequence. Accordingly, claims 2-4 do not further limit claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as

to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation "comprising at least", and the claim also recites "or a fragment thereof" which is the narrower statement of the range/limitation.

Claim 18 is indefinite because polynucleotides cannot be cultured.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 3 and 5 remain, and newly introduced claims 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Brigstock et al., U.S. Patent Number 5,876,730 for reasons cited in the previous Office Action, mailed 10/23/01, at page(s) 4. It is noted that claim 3 is not further limiting of claim 1, and accordingly has been interpreted independently of claim 1's limitation that it comprise the (complete) amino acid sequence of SEQ ID NO: 4. With respect to claim 15 and its dependents, HBGF as disclosed by Brigstock is residues 247 or 248 to the terminus of SEQ ID NO: 2 of this application, which is a fragment of (b) of claim 15, as recited in part (d) of that claim. Applicants traversal at page 4 of paper number 20, submitted 5/9/02 is not persuasive, as the claims are anticipated by Brigstock et al. for reasons above.

Claims 1 and 5 remain, and newly introduced claims 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Grotendorst et al., U.S. Patent Number 5,408,040 for reasons cited in the previous Office Action, mailed 10/23/01, at page(s) 5. Applicants argument at page 4 of paper number 20 to the effect that "the present invention is directed toward a unique group of CTGF fragments not delineated by Grotendorst et al" has been fully considered but is not deemed persuasive because there are no functional or structural limitations to delineate the claimed invention from the fragments of Grotendorst, all of which would "not consist of SEQ ID NO: 2" of this application, and a majority of which would comprise at least a fragment of residues 4-74 or 75-172 of SEQ ID NO: 4, as Grotendorst envisions functional fragments, which would inherently comprise at least exon 5, which is the portion of the molecule (as identified by Brigstock) with mitogenic activity.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Grotendorst et al., U.S. Patent Number 5,408,040 in view of Brigstock et al., U.S. Patent Number 5,876,730 5,408,040 for reasons cited in the previous Office Action, mailed 10/23/01, at page(s) 5-6. Applicants arguments have been fully considered but are not deemed persuasive because, contrary to applicants argument, the Examiner does not find the claims to be directed to any specific

fragments, as all three claims either state "of a fragment thereof" or "comprising", and , as stated in the previous Office Action, as Grotendorst et al. specifically suggest making functional fragments of CTGF, the Examiner finds that, using only the teachings of Grotendorst and routine experimentation (deleting portions of the protein and testing for activity), one of ordinary skill in the art would arrive at numerous species within the metes and bounds of the rejected claims. Further, given Brigstock's disclosure that HBGF , which is residues 247-349 of CTGF has mitogenic activity, one would expect success at making such fragments, and additionally would expect that fragments comprising at least residues 247-349, which comprise the entirety of the portion of the protein encoded by exon 5, would be active. Accordingly, the invention, taken as a whole, remains *prima facie* obvious over the cited prior art.

Double Patenting Rejections:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 15-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 15-18 of copending Application No. 09/461688. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to fragments of CTGF and

nucleic acids encoding such. Although the two applications require different biological activities of those fragments, and are thus of different scope, there is substantial overlap in the actual fragments that are encompassed by the two sets of claims. Applicants willingness to file a terminal disclaimer is noted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Advisory Information:

No claim is allowed.

It is noted that the claims are drawn to fragments of CTGF which are mitogenically active. It is further noted that the sole working example in the specification is drawn to a protein consisting of the protein encoded by exons 4 and 5. There are no working examples of any shorter protein. However, based upon the knowledge in the art of HBGF, which is the protein encoded by exon 5, and which has mitogenic activity, it is quite predictable that any protein comprising the protein encoded by exon 5 will have activity. However, it is not predictable that a protein comprising exon 4 but *not* exon 5 would have any such activity, nor does the specification teach or provide guidance as to what minimum portion of exon 5 is required for activity. Accordingly, applicants are cautioned that amendment of claims to be limited to a protein "consisting" of the protein encoded by exon 4 or a fragment thereof (or any other claim language that would exclude the presence of exon 5) would be found not to be enabled under 35 U.S.C. § 112, first paragraph.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS

from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

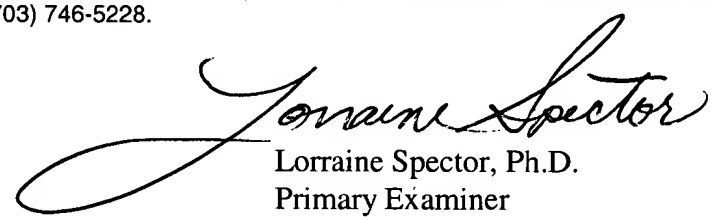
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.



Lorraine Spector, Ph.D.
Primary Examiner

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